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Rapid urine-based Screening for Tuberculosis to reduce AIDS-related Mortality in hospitalized Patients in Africa (STAMP) trial

Submission date
22/04/2015

Recruitment status
No longer recruiting

Registration date
08/05/2015

Overall study status
Completed

Last Edited
07/07/2025

Condition category
Infections and Infestations

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sub-Saharan Africa bears the brunt of the global HIV/AIDS epidemic and tuberculosis (TB) is the leading cause of AIDS-related illness and deaths worldwide. Studies from across the continent have shown that between one-and two-thirds of HIV-infected adult hospital in-patients who die have evidence of TB at post-mortem. Much of this disease is neither clinically suspected nor diagnosed before death. This indicates a failure of current approaches to diagnosis, which is the key problem addressed by this trial. We believe that recent advances in TB diagnosis can be harnessed to address this challenge in a fundamentally new way. Studies in South Africa have found that the number of HIV-infected patients confirmed to have TB needing to be admitted to hospital was extremely high (32%). However, they also found symptoms were a poor predictor of the disease and that, in day-to-day clinical practice, many cases are not diagnosed. We propose that, regardless of symptoms, all such patients should be investigated for TB on admission. In these studies the number of patients diagnosed using the traditional approach of sputum-based testing was limited as fewer than half of the patients could produce sputum samples, and also because much of the disease involved organs other than the lungs. In contrast, urine samples could be obtained from almost all patients and testing these with rapid diagnostics (a simple 30-minute 'dipstick' test, Determine TB-LAM Ag test, and the recently WHO-approved Xpert MTB/RIF test) increased the number of early diagnoses of TB substantially. The aim of this study is find out whether we can reduce the number of early deaths by screening all HIV-infected patients admitted to medical wards in hospital using these rapid urine-based tests.

Who can participate?
Adult HIV-infected medical inpatients admitted to two regional referral hospitals in South Africa and Malawi.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (control) are screened for TB using the Xpert testing of sputum (the current 'standard' care according to guidelines). Those in group 2 (intervention) also undergo Xpert testing and also additional

screening with a combination of the two urine-based diagnostic tests. The care of patients provided by the routine medical team is not otherwise altered. The results are analysed to see whether the additional urine-based screening results in greater patient survival due to an increase in number and early diagnosis of TB.

What are the possible benefits and risks of participating?
We anticipate that patients in the intervention group with HIV-associated TB will benefit from urine-based screening due to an increased number being diagnosed or being diagnosed early, and being given early treatment. However we cannot guarantee any benefits from this study. Risk of harm to patients in this study is low. The study requirement for samples of blood, sputum and urine from patients is not associated with any risks to patient safety. However, it is possible that such screening may inadvertently be harmful in the following ways: a very small proportion of screening tests may give false-positive results, leading to inappropriate treatment for TB (anticipated to be less than 1 per 100) or for MDR-TB, rapid TB diagnosis may result in other concurrent pathologies being overlooked or reduce the likelihood that patients receive a course of simple antibiotics as part of the diagnostic work-up.

Where is the study run from?
The Zomba Central Hospital (Malawi) and Edendale Regional Hospital (South Africa)

When is the study starting and how long is it expected to run for?
February 2015 to January 2018

Who is funding the study?
Global Health Trials (Wellcome Trust, the UK Department for International Development and the UK Medical Research Council)

Who is the main contact?
Dr Katherine Fielding

Contact information

Type(s)
Scientific

Contact name
Dr Katherine Fielding

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
LOI:13.016 / pFACT6451 / ITCRZE64

Study information

Scientific Title
Rapid urine-based Screening for Tuberculosis to reduce AIDS-related Mortality in hospitalized Patients in Africa (STAMP): a pragmatic, multicentre, individually randomized clinical trial

Acronym
STAMP

Study objectives
The implementation of a rapid, sensitive urine-based screening strategy for TB, used in combination with routine sputum-based standard of care diagnosis, can reduce all-cause mortality among HIV-infected medical in-patients newly admitted to hospitals in southern African countries.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. London School of Hygiene & Tropical Medicine Research Ethics Committee, 05/05/2015, ref: 9630
2. College of Medicine Research Ethics Committee (Malawi), 03/08/2015, ref: P.06/15/1743
3. University of KwaZulu-Natal Biomedical Research Ethics Committee (South Africa), 09/09/2015, ref: BFC215/15

Study design
Pragmatic multicentre individually randomized clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
HIV-associated tuberculosis

Interventions
A screening strategy for HIV-infected adult patients requiring acute admission to hospital medical wards, based on testing of urine with the Determine TB-LAM lateral-flow assay and Xpert MTB/RIF assay and testing of sputum with Xpert MTB/RIF assay (intervention arm). This will be compared to sputum testing alone (standard of care arm).

Intervention Type
Procedure/Surgery

Primary outcome measure
Risk of all-cause mortality at 56 days after randomization from any cause, compared between arms.

Secondary outcome measures
1. Time to all-cause mortality
2. Proportions of patients with:
2.1. Microbiologically confirmed diagnosis of TB
2.2. Clinically diagnosed TB disease
3. Time from randomisation to:
3.1. TB diagnosis
3.2. Start of TB treatment in days
4. Proportion of patients receiving:
4.1. Antibacterial treatment
4.2. In ART naïve patients, proportion starting ART and time to ART initiation in days
5.1. Duration of hospital stay in days
5.2. Cumulative incidence of hospital readmission (c) cumulative incidence of loss to follow-up

All measured at 56 days after randomization

Overall study start date
01/02/2015

Completion date
31/01/2018

Eligibility

Key inclusion criteria
1. Requires acute admission to a hospital medical ward
2. Have confirmed HIV-infection
3. Willing and able to provide informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2600

Key exclusion criteria
1. Aged <18 years
2. Has been admitted to a medical ward for longer than 48 hours
3. Has received treatment for TB within the preceding 12 months, or has received isoniazid preventative therapy (IPT) within the last 6 months
4. Residence does not lie within a pre-defined geographic area or plans to leave this area during the period of trial follow-up
5. Unable or unwilling to provide informed consent

Date of first enrolment
01/09/2015

Date of final enrolment
31/07/2017

Locations

Countries of recruitment
Malawi

South Africa

Study participating centre
Zomba Central Hospital
Malawi
-

Study participating centre
Edendale Regional Hospital
South Africa
-

Sponsor information

Organisation
London School of Hygiene & Tropical Medicine

Sponsor details
Clinical Trials Unit
Keppel Street
London
England
United Kingdom
WC1E 7HT

Sponsor type
University/education

Website
http://www.lshtm.ac.uk

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Charity

Funder Name
Wellcome Trust

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
International organizations

Location
United Kingdom

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Study results will be disseminated to relevant local, national and international policymakers and will also be rapidly made available through presentations at relevant international conferences and regional conferences in southern Africa. The main trial results will be published in an appropriate peer-reviewed scientific journal as soon as possible following completion of the trial and analysis of the results.

Intention to publish date
31/01/2019

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	22/09/2016		Yes	No

Results article	results	28/07/2018		Yes	No
Results article	tuberculosis in HIV-positive patients on the first day of acute hospital admission	14/08/2015	07/07/2025	Yes	No